

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 640100-346	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/US 99/ 26927	International filing date (day/month/year) 12/11/1999	(Earliest) Priority Date (day/month/year) 13/11/1998
Applicant OSIRIS THERAPEUTICS, INC. et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of Invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☒ None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/26927

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K35/12 A61K35/28 A61K48/00 A01K67/027 C12N5/00
C12N15/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K A01K C12N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	SROUR E F ET AL.: "Sustained human hematopoiesis in sheep transplanted in utero during early gestation with fractionated adult human bone marrow cells" BLOOD, vol. 79, no. 6, 15 March 1992 (1992-03-15), pages 1404-1412, XP000569644 the whole document --- -/--	1-8



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

9 June 2000

Date of mailing of the international search report

27/06/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
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Fax: (+31-70) 340-3016

Authorized officer

Teyssier, B

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	PROCKOP D J: "Marrow stromal cells as stem cells for nonhematopoietic tissues" SCIENCE, vol. 276, no. 5309, 4 April 1997 (1997-04-04), pages 71-74, XP002139788 ~	1-3
A	pages 73-74, "Potential uses in cell and gene therapy"	4-8, 24-27
X	PEREIRA R F ET AL.: "Cultured adherent cells from marrow can serve as long-lasting precursor cells for bone, cartilage, and lung in irradiated mice" PROC. NAT'L. ACAD. SCI. USA, vol. 92, May 1995 (1995-05), pages 4857-4861, XP002139789	1-3
A	cited in the application pages 4859-4861, "Discussion"	4-8, 24-27
A	WO 97 10348 A (UNIV CALIFORNIA) 20 March 1997 (1997-03-20) page 3, line 31 -page 5, line 14 page 8, line 21 -page 11, line 27	1-8, 24-27
A	WO 94 26884 A (BIOTECHNOLOGY RES & DEV) 24 November 1994 (1994-11-24) page 1 -page 4, line 26 page 7, line 8 - line 27; claims 1,35	9-23
P,X	LIECHTY K W ET AL.: "Distribution and engraftment of human mesenchymal stem cells (MSC) after in utero transplantation in fetal sheep." BLOOD, vol. 92, no. 10 Suppl. 1, 15 November 1998 (1998-11-15), page 117A XP000914604 40th annual meeting of the American Society of Hematology, 4-8/12/1998 abstract 474	1-27
P,X	WO 99 46366 A (OSIRIS THERAPEUTICS INC) 16 September 1999 (1999-09-16) page 1 -page 2, line 21 page 11, line 15 -page 13, line 28	1-3

-/--

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
T	<p>ALMEIDA-PORADA G ET AL: "Human bone marrow stromal cell progenitors are able to induce donor specific tolerance after in utero transplantation." BLOOD, vol. 94, no. 10 SUPPL. 1 PART 1, 15 November 1999 (1999-11-15), page 40a XP002139877 41th annual meeting of the American Society of Hematology, 3-7/12-1999 abstract 167</p> <p>---</p>	
T	<p>DEVINE S ET AL.: "Studies of mesenchymal stem cells in non-human primates: Evaluation of toxicity and engraftment" BLOOD, vol. 94, no. 10 Suppl. 1, 15 November 1999 (1999-11-15), page 391a XP002139790 41th annual meeting of the American Society of Hematology, 3-7/12/1999 abstract 1733</p> <p>-----</p>	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/26927

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
✓ WO 9710348	A	20-03-1997	AU 7238796 A	01-04-1997
✓ WO 9426884	A	24-11-1994	US 5523226 A	04-06-1996
			AT 184647 T	15-10-1999
			AU 694126 B	16-07-1998
			AU 7019394 A	12-12-1994
			DE 69420726 D	21-10-1999
			DE 69420726 T	27-04-2000
			EP 0701608 A	20-03-1996
			ES 2140542 T	01-03-2000
			US 5942435 A	24-08-1999
✓ WO 9946366	A	16-09-1999	AU 2904299 A	27-09-1999

PCT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents
United States Patent and Trademark
Office
Box PCT
Washington, D.C.20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 01 September 2000 (01.09.00)	
International application No. PCT/US99/26927	Applicant's or agent's file reference 640100-346
International filing date (day/month/year) 12 November 1999 (12.11.99)	Priority date (day/month/year) 13 November 1998 (13.11.98)
Applicant THIEDE, Mark et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
09 June 2000 (09.06.00)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Manu Berrod
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

5000
09/830139

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference 640100-346	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US99/26927	International filing date (day/month/year) 12 NOVEMBER 1999	Priority date (day/month/year) 13 NOVEMBER 1998
International Patent Classification (IPC) or national classification and IPC Please See Supplemental Sheet.		
Applicant OSIRIS THERAPEUTICS, INC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 8 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 09 JUNE 2000	Date of completion of this report 05 SEPTEMBER 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer JOSEPH T. WOITACH
Facsimile No. (703) 305-3230	Telephone No. (703) 308-0196

I. Basis of the report**1. With regard to the elements of the international application:***☐ the international application as originally filed☒ the description:pages 1-29, as originally filedpages NONE, filed with the demandpages NONE, filed with the letter of _____☒ the claims:pages 30-31, as originally filedpages NONE, as amended (together with any statement) under Article 19pages NONE, filed with the demandpages NONE, filed with the letter of _____☒ the drawings:pages 1-10, as originally filedpages NONE, filed with the demandpages NONE, filed with the letter of _____☒ the sequence listing part of the description:pages NONE, as originally filedpages NONE, filed with the demandpages NONE, filed with the letter of _____**2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.**

These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).☐ the language of publication of the international application (under Rule 48.3(b)).☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).**3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:**☐ contained in the international application in printed form.☐ filed together with the international application in computer readable form.☐ furnished subsequently to this Authority in written form.☐ furnished subsequently to this Authority in computer readable form.☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.**4. ☒ The amendments have resulted in the cancellation of:**☒ the description, pages NONE☒ the claims, Nos. NONE☒ the drawings, sheets/fig NONE**5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).****

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

**Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. statement**

Novelty (N)	Claims	<u>NONE</u>	YES
	Claims	<u>1-27</u>	NO
Inventive Step (IS)	Claims	<u>NONE</u>	YES
	Claims	<u>1-27</u>	NO
Industrial Applicability (IA)	Claims	<u>1-27</u>	YES
	Claims	<u>NONE</u>	NO

2. citations and explanations (Rule 70.7)

Claims 1-27 lack novelty under PCT Article 33(2) as being anticipated by Liechty et al., WO 99/46366, and Srour et al.

Each Liechty et al., WO 99/46366, and Srour et al. anticipates claims 1-27. Claims 1-8 encompass a method for treating a fetus comprising administering mesenchymal stem cells to the fetus. No treatment step is recited therefore administration of mesenchymal stem cells into a non-human fetus (claim 4) for any reason is sufficient to meet the limitations of claims 1-8. Claims 9-23 encompass a method for preparing an organ for transplantation comprising administering mesenchyma stem cells in utero and harvesting the said organ. Claims 9-23 differ from the method of claims 1-8 only in that the organ is harvested. Claims 24-27 are product claims and encompass a hybrid organ comprising an organ from one species and mesenchymal stem cells from a second species. In light of the specification, following the methods encompassed by claims 1-8 or 9-23 would inherently result in the chimeric organ of claims 24-27. Liechty et al. teach that transplantation of mesenchymal stem cells in fetal sheep results in distribution and engraftment of the stem cell to various organs throughout the sheep up to 85 days. WO 99/46366 teaches transplantation of non-autologous mesenchymal stem cells to a patient in need thereof. It is taught that systemic administration of the mesenchyma stem cells results in migration to various tissues within the host (page 9, lines 1-9). Finally, in the working examples, results demonstrating that the resulting tissues after transplantation are chimeric provided the basis of using the organs for transplantation scenarios (page 34, lines 21-28). Srour et al. teach human mesenchymal stem cells transplanted into sheep in utero results in the ability of the transplanted cells to undergo hematopoiesis. The bone marrow is harvested and analyzed to demonstrate the karyotype of cells is chimeric, both human and ovine (TABLEs 1 and 2). While other tissues are not examined for chimerism, since the same method steps are used as recited in the claims that other tissues would also inherently result in chimeric organs.

----- NEW CITATIONS -----
NONE

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: Boxes I - VIII

Sheet 10

CLASSIFICATION:

The International Patent Classification (IPC) and/or the National classification are as listed below:

IPC(7): A61K 35/12, 35/28, 48/00; A01K 67/027; C12N 5/00, 15/00 and US Cl.: 424/493.1; 435/325, 455



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61K 35/12, 35/28, 48/00, A01K 67/027, C12N 5/00, 15/00	A3	(11) International Publication Number: WO 00/29002 (43) International Publication Date: 25 May 2000 (25.05.00)
(21) International Application Number: PCT/US99/26927 (22) International Filing Date: 12 November 1999 (12.11.99) (30) Priority Data: 60/108,357 13 November 1998 (13.11.98) US (71) Applicant (for all designated States except US): OSIRIS THERAPEUTICS, INC. [US/US]; 2001 Aliceanna Street, Baltimore, MD 21231-2001 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): THIEDE, Mark [US/US]; 12572 Markaire Drive, St. Louis, MO 63146 (US). FLAKE, Alan [US/US]; 1131 Springmont Circle, Bryn Mawr, PA 19010 (US). (74) Agents: LILLIE, Raymond et al.; Carella, Byrne, Bain, Gilfillan, Cecchi, Stewart & Olstein, 6 Becker Farm Road, Roseland, NJ 07068 (US).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> (88) Date of publication of the international search report: 5 October 2000 (05.10.00)
(54) Title: <i>IN UTERO</i> TRANSPLANTATION OF HUMAN MESENCHYMAL STEM CELLS (57) Abstract The present invention is directed to mesenchymal stem cells for transplantation <i>in utero</i> . Such mesenchymal stem cells may be employed in a method of treating a fetus, or in a method of engrafting mesenchymal stem cells, or in a method of preparing an organ for transplantation.		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
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BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
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CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakhstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/US 99/26927

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K35/12 A61K35/28 A61K48/00 A01K67/027 C12N5/00
C12N15/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K A01K C12N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>SROUR E F ET AL.: "Sustained human hematopoiesis in sheep transplanted in utero during early gestation with fractionated adult human bone marrow cells"</p> <p>BLOOD, vol. 79, no. 6, 15 March 1992 (1992-03-15), pages 1404-1412, XP000569644 the whole document</p> <p style="text-align: center;">--- -/--</p>	1-8

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
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Z document member of the same patent family

Date of the actual completion of the international search

9 June 2000

Date of mailing of the international search report

27/06/2000

Name and mailing address of the ISA

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Fax: (+31-70) 340-3016

Authorized officer

Teyssier, B

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 99/26927

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X	PEREIRA R F ET AL.: "Cultured adherent cells from marrow can serve as long-lasting precursor cells for bone, cartilage, and lung in irradiated mice" PROC. NAT'L. ACAD. SCI. USA, vol. 92, May 1995 (1995-05), pages 4857-4861, XP002139789	1-3
A	cited in the application pages 4859-4861, "Discussion"	4-8, 24-27
A	WO 97 10348 A (UNIV CALIFORNIA) 20 March 1997 (1997-03-20) page 3, line 31 -page 5, line 14 page 8, line 21 -page 11, line 27	1-8, 24-27
A	WO 94 26884 A (BIOTECHNOLOGY RES & DEV) 24 November 1994 (1994-11-24) page 1 -page 4, line 26 page 7, line 8 - line 27; claims 1,35	9-23
P,X	LIECHTY K W ET AL.: "Distribution and engraftment of human mesenchymal stem cells (MSC) after in utero transplantation in fetal sheep." BLOOD, vol. 92, no. 10 Suppl. 1, 15 November 1998 (1998-11-15), page 117A XP000914604 40th annual meeting of the American Society of Hematology, 4-8/12/1998 abstract 474	1-27
P,X	WO 99 46366 A (OSIRIS THERAPEUTICS INC) 16 September 1999 (1999-09-16) page 1 -page 2, line 21 page 11, line 15 -page 13, line 28	1-3

-/--

INTERNATIONAL SEARCH REPORT

Inte onal Application No
PCT/US 99/26927

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
T	<p>ALMEIDA-PORADA G ET AL: "Human bone marrow stromal cell progenitors are able to induce donor specific tolerance after in utero transplantation." BLOOD, vol. 94, no. 10 SUPPL. 1 PART 1, 15 November 1999 (1999-11-15), page 40a XP002139877 41th annual meeting of the American Society of Hematology, 3-7/12-1999 abastract 167</p> <p style="text-align: center;">---</p>	
T	<p>DEVINE S ET AL.: "Studies of mesenchymal stem cells in non-human primates: Evaluation of toxicity and engraftment" BLOOD, vol. 94, no. 10 Suppl. 1, 15 November 1999 (1999-11-15), page 391a XP002139790 41th annual meeting of the American Society of Hematology, 3-7/12/1999 abstract 1733</p> <p style="text-align: center;">-----</p>	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/26927

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
W0 9710348 A	20-03-1997	AU 7238796 A	01-04-1997
W0 9426884 A	24-11-1994	US 5523226 A	04-06-1996
		AT 184647 T	15-10-1999
		AU 694126 B	16-07-1998
		AU 7019394 A	12-12-1994
		DE 69420726 D	21-10-1999
		DE 69420726 T	27-04-2000
		EP 0701608 A	20-03-1996
		ES 2140542 T	01-03-2000
		US 5942435 A	24-08-1999
W0 9946366 A	16-09-1999	AU 2904299 A	27-09-1999